



Subject: Alliance for Biosecurity, RFI # 75A50120NEXTGENSNS,

The Alliance for Biosecurity (Alliance) is a coalition of biopharmaceutical companies and laboratory/academic partners that promotes a strong public-private partnership to ensure medical countermeasures (MCMs) are available to protect public health and enhance national health security. The Alliance advocates for public policies and funding to support the rapid development, production, stockpiling, and distribution of critically needed MCMs.

The Alliance appreciates the opportunity to submit comments in response to the Request for Information (RFI) from the Department of Health and Human Services (HHS) and Assistant Secretary for Preparedness and Response (ASPR) regarding the “Strategic National Stockpile (SNS) 2.0” (NextGen SNS) initiative. The SNS is the nation’s largest supply of potentially life-saving pharmaceuticals and medical supplies for use in a public health emergency severe enough to cause local supplies to run out. And, as we have seen during the COVID-19 public health emergency, its role in supplementing state and local supplies during such public health emergencies cannot be overstated. We are therefore supportive of this important initiative to restock and revamp the SNS and to improve SNS inventory management and distribution.

That said, the Alliance is concerned with the Next Gen SNS’s proposed approach, as it fails to take into account the unique considerations associated with those countermeasures for which the SNS is *the* repository. As you know, Project BioShield was established to allow HHS to conduct and support research, development, and procurement activities for MCMs “to treat, identify, or prevent harm from any biological, chemical, radiological or nuclear (CBRN) agent that may cause a public health emergency affecting national security.” The program effectively creates a guaranteed market incentive for pharmaceutical companies to produce CBRN MCMs for which there is no commercial market.

The proposed approach to restocking the SNS and managing its inventory and distribution largely appears to focus on durable goods for which there is already a commercial market (personal protective equipment (PPE), ventilators, testing supplies, etc.). While the Supply Chain IT Control Tower concept in conjunction with industry partnerships may be helpful to building inventory and/or capacity at different points in the value chain for many products in the SNS, the approach will create challenges for MCM manufacturers of unique countermeasures – such as those against anthrax, smallpox, botulinum toxin, etc. – for which there is no commercial market and for which the SNS is *the* repository. Thus, to the extent that HHS and ASPR move forward with the proposed approach, the Alliance suggests that there be a distinction made between the approach to stockpiling these bespoke MCMs and those off-the-shelf MCMs for which there is a commercial market.

The Alliance appreciates the NextGen SNS’s recognition and plan to expand the use of public-private partnerships. We believe that these partnerships for the development and availability of MCMs are a core element of global health security. Alliance member companies contribute significantly to preparedness and response capabilities against a variety of CBRN threats, as well as naturally occurring threats such as pandemic influenza and various other emerging infectious

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diseases (EIDs). By leveraging our collective knowledge and expertise, the Alliance is committed to building and strengthening these critical partnerships between government and the biopharmaceutical industry, and to help identify and provide solutions to the threats facing our nation. These partnerships support the essential mission of the SNS in ensuring the availability of needed MCMs during times of crisis.

Finally, though beyond the scope of the RFI, the Alliance recognizes that the SNS has traditionally been underfunded when compared to the funding levels proposed in the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) multiyear budget. With finite resources available to deal with an ever-expanding set of issues, the Alliance believes that the funding levels proposed and validated by the PHEMCE – the entity charged with coordinating Federal efforts to enhance CBRN and EID preparedness from a MCM perspective – should be requested by the Administration and appropriated by Congress. As such, the Alliance supports \$1.081 billion in SNS funding for FY 20201. The SNS is a critical leg in the MCM enterprise and, if we develop the capability but do not procure or maintain the stock for an emergency, we put Americans at risk and risk wasting the up front-end investment.

In conclusion, the Alliance very much appreciates your interest in, and support for, providing the resources necessary to respond to public health emergencies. We look forward to working with you to advance these critical priorities for our nation.

Sincerely,



The Honorable Jack Kingston
Squire Patton Boggs
Secretariat, Alliance for Biosecurity